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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products
Liability Litigation

No. MD-15-02641-PHX-DGC

**PLAINTIFFS' OMNIBUS
STATEMENT OF LAW AND
GENERALLY-APPLICABLE
ARGUMENTS IN OPPOSITION TO
BARD'S MOTIONS TO EXCLUDE
PLAINTIFFS' EXPERTS UNDER
RULE 702 AND DAUBERT**

Plaintiffs hereby submit their omnibus statement of the applicable law and generally-applicable arguments in opposition to Defendants' various motions to exclude the opinions of Plaintiffs' experts under Fed. R. Evid. 702. Pursuant to the Court's instructions in CMO 26 (Doc. 6799), the purpose of this submission is to streamline the case-specific bellwether Rule 702/*Daubert* briefing by addressing general issues once, herein, and then incorporating by reference those arguments into the expert-specific response briefs.

I. THE LAW APPLICABLE TO ALL RULE 702/DAUBERT MOTIONS.

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness

1 qualified as an expert by knowledge, skill, experience, training or education,
2 may testify thereto in the form of an opinion or otherwise.

3 Fed. R. Evid. 702; *see also Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993).

4 If the proffered expert's opinions rests on a reliable foundation and are helpful to the jury,
5 the expert's testimony is admissible. *City of Pomona v. SQM North America Corp.*, 750
6 F.3d 1036, 1043 (9th Cir. 2014); *see also Placencia v. I-Flow Corp.*, No. CV10-2520
7 PHX DGC, 2012 WL 5877624, at *8 (D. Ariz. Nov. 20, 2012) (describing the Rule
8 702/*Daubert* standard).

9 *Daubert* intended to loosen, not tighten, the rules governing admission of expert
10 testimony, 509 U.S. at 588, and the court's inquiry into admissibility "is a flexible one,"
11 *Alaska Rent-A-Car, Inc. v. Avis Budget Grp., Inc.*, 738 F.3d 960, 969 (9th Cir. 2013).
12 Exclusion is not favored but rather "[v]igorous cross-examination, presentation of
13 contrary evidence, and careful instruction on the burden of proof are the traditional and
14 appropriate means of attacking shaky but admissible evidence." *Placencia*, 2012 WL
15 5877624 at *12 (quoting *Daubert*, 509 U.S. at 596; quotation marks omitted).

16 The focus of the *Daubert* inquiry must be solely on the principles and methodology
17 the expert followed, not the conclusions they generate. *Daubert*, 509 U.S. at 595. For
18 that reason, the district court must not decide whether the expert is right or wrong, but
19 whether the expert's testimony "has substance such that it would be helpful to a jury."
20 *Alaska Rent-A-Car, Inc.*, 738 F.3d at 969-70. As this Court observed, "In serving its
21 gatekeeping function, the court must be careful not to cross over into the role of
22 factfinder. It is not the job of the court to insure that the evidence heard by the jury is
23 error-free, but to insure that it is not wholly unreliable." *Bernal v. Daewoo Motor*, No.
24 CV09-1502 PHX-DGC, 2011 WL 2174890, at *18 (D. Ariz. June 2, 2011) (quotation
25 marks and citation omitted)); *see also Placencia*, 2012 WL 5877624 at *12 (noting that
26 "[n]either *Daubert* nor Rule 702 demands absolute evidence of causation before an
27 expert's testimony can be admitted").
28

1 Courts should not apply standards that are more exacting than those scientists apply
 2 in their work outside the courtroom; rather, they should assess whether the challenged
 3 opinion “falls within the range of accepted standards governing how scientists conduct
 4 their research and reach their conclusions.” *Daubert v. Merrell Dow Pharms., Inc.*, 43
 5 F.3d 1311, 1317 (9th Cir. 1995) (“*Daubert II*”). Like science in other contexts, studies
 6 and research relied on or conducted by scientific or technical experts in litigation are not
 7 required by *Daubert* to be flawless and certain. *See* Federal Judicial Center, *Reference*
 8 *Manual on Scientific Evidence* 553 (3d ed. 2011). “[A]ll studies have ‘flaws’ in the sense
 9 of limitations that add uncertainty about the proper interpretation of the results. Some
 10 flaws are inevitable given the limits of technology, resources, the ability and willingness
 11 of persons to participate in a study, and ethical constraints.” *Id.* (citing *In re*
 12 *Phenylpropanolamine (PPA) Prods. Liab. Litig.*, 289 F. Supp. 2d 1230, 1240 (W.D.
 13 Wash. 2003) (quoting *Reference Manual* and criticizing defendant’s “ex post facto
 14 dissection” of a study); *In re Orthopedic Bone Screw Prods. Liab. Litig.*, MDL No. 1014,
 15 1997 WL 230818, at *8 (E.D. Pa. May 5, 1997) (holding that despite potential for several
 16 biases in a study that “may . . . render its conclusions inaccurate,” the study was
 17 sufficiently reliable to be admissible); Joseph L. Gastwirth, *Reference Guide on Survey*
 18 *Research*, 36 *Jurimetrics J.* 181, 185 (1996) (review essay) (“One can always point to a
 19 potential flaw in a statistical analysis.”)).

20 Throughout its briefs, Bard demands that the Court mechanically apply every one
 21 of *Daubert*’s list of factors for assessing reliability to nearly every single Plaintiffs expert.
 22 But the Supreme Court emphasized that these factors were not intended to be a “definitive
 23 checklist or test.” *Daubert*, 509 U.S. at 593. District courts have flexibility to apply the
 24 *Daubert* factors, which are intended to be “exemplary, not constraining.” *Murray v. S.*
 25 *Route Mar. SA*, ___ F. 3d. ___, ___, No. 14-36056, 2017 WL 3758326, at *5 (9th Cir.
 26 Aug. 31, 2017) (citing *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999)); *see*
 27 *also Alaska Rent-A-Car, Inc.*, 738 F.3d at 969 (noting that the Rule 702 factors “make[]
 28 the task of determining admissibility sound more mechanical and less judgmental than it

really is”); *Primano v. Cook*, 598 F.3d 558, 564 (9th Cir. 2010) (noting that the *Daubert* “list of factors was meant to be helpful, not definitive” (quotation marks omitted; quoting *Kumho Tire*, 526 U.S. at 151)). These suggested factors for courts to consider are not “equally applicable (or applicable at all) in every case” or to every expert. *Daubert II*, 43 F.3d at 1317. “Because of the fluid and contextual nature of the inquiry, district courts are vested with broad latitude to decide how to test an expert’s reliability and whether or not an expert’s relevant testimony is reliable.” *Murray*, ___ F. 3d at ___, 2017 WL3758326, at *5 (quoting *Kumho Tire Co.*, 526 U.S. at 150, 152-153; alterations, citations, and quotation marks omitted). The applicability of different types of tests for reliability “depends on the nature of the issue, the expert’s particular expertise, and the subject of his testimony,” and a “district court may permissibly choose not to examine factors that are not reasonable measures of reliability in a particular case.” *Id.*

When evaluating the expert testimony of physicians in particular, courts should broadly admit medical expert testimony if it is useful and reliable “but it need not be conclusive because medical knowledge is often uncertain.” *Primiano v. Cook*, 598 F.3d 558, 565 (9th Cir. 2010), *as amended* (Apr. 27, 2010) (quotation marks omitted). “Where the foundation is sufficient, the litigant is entitled to have the jury decide upon the experts’ credibility, rather than the judge.” *Id.* (alterations and quotation marks omitted). A physician’s testimony does not have to rely solely on opinions developed independent of litigation, peer-reviewed publications, or animal or epidemiological studies to be admissible. Expert physician testimony can be (and often is) based on an expert’s clinical experience. *Wendell v. GlaxoSmithKline LLC*, 858 F.3d 1227, 1235-37 (9th Cir. 2017) (reversing district court’s grant of motions to exclude plaintiff’s causation experts). Excluding a physician expert because the expert’s opinion was based on clinical experience is an abuse of discretion. *Id.* at 1237 (reversing district court’s grant of motions to exclude Plaintiff’s causation experts; “Where, as here, two doctors who stand at or near the top of their field and have extensive clinical experience with the rare disease

1 or class of disease at issue, are prepared to give expert opinions supporting causation, we
 2 conclude that *Daubert* poses no bar based on their principles and methodology.”).

3 **II. ARGUMENTS GENERALLY APPLICABLE TO ALL OR SEVERAL** 4 **BARD MOTIONS**

5 **A. Plaintiffs’ physician experts are allowed to testify about what a** 6 **“reasonable physician” would have expected.**

7 Bard maintains that no expert may testify that they and their colleagues reasonably
 8 expected Bard to provide accurate and up-to-date information to physicians about the risks
 9 of its IVC filters because there is no written standard that defines what a “reasonable
 10 physician” would do with this information. And Bard further argues that Plaintiffs’
 11 experts cannot point to a peer-reviewed study to support all of their conclusions. Bard’s
 12 arguments are without merit.

13 Physician expert witnesses routinely opine about what a “reasonable doctor” would
 14 have done or what a reasonable physician would have expected in a particular situation in
 15 medical malpractice and many other types of litigations. Indeed, Arizona law requires
 16 such expert testimony as a predicate for filing a medical malpractice action or any other
 17 lawsuit against a licensed professional. *See* A.R.S. §§ 12-2602, -2603. But without citing
 18 any authority, Bard argues that the “reasonable physician” standard in this case is different
 19 than in a medical malpractice case. Bard is mistaken. The type of expert testimony
 20 required for a product liability case involving warning defects is no different than in a
 21 medical malpractice case, particularly on the subject of informed consent. *See* Exhibit 1
 22 hereto, Deposition of Mark W. Moritz, M.D., July 18, 2017 (“Moritz Dep.”) at 43:6-
 23 44:22; 52:8-19 (Bard expert testifying that reasonable expectations of doctors, the medical
 24 community and patients are that medical device manufacturers will be open and honest
 25 and provide complete, accurate, and thorough information about their devices so that
 26 doctors and patients can discuss likelihood of risks with the device as part of informed
 27 consent process); *see also id.* at 66:7-16, 71:6-24 (doctors and patients have reasonable
 28 expectations that medical device will be as safe and effective as predicate device); *id.* at

85:12-86:3 (Dr. Moritz saw in reviewing Plaintiffs’ experts’ reports Bard internal documents describing serious injuries and deaths and those are documents that would be important to medical doctors in making decisions to use Bard’s IVC filters). In both kinds of cases, the expert witness is offering his or her opinion on how a doctor should or would respond to a certain situation. And the foundation for a medical expert’s opinion is the same, including professional guidelines, clinical experience and education, peer-reviewed literature, and interactions with colleagues in the relevant community. *See Primiano v. Cook*, 598 F.3d 558, 567 (9th Cir. 2010) (holding that physician’s testimony must be admitted based on his background, experience, and explanation of his opinion). Rule 702/*Daubert* cannot be used to justify the exclusion of an expert’s standard of care opinions in a medical malpractice case—or a lawyer expert’s standard of care opinion in a legal malpractice case—just because the physician or lawyer expert can’t point to a peer-reviewed survey of physicians or lawyers nationwide to support their opinion. *See Saint Alphonsus Med. Ctr.- Nampa, Inc. v. St. Luke’s Health System, Ltd.*, No. 1:12-CV-00560-BLW, 2014 WL 407446, at *18 (D. Idaho Jan. 24, 2014) (basing conclusion of law on defense expert’s testimony that “all physicians” at the defendant-hospital needed to obtain access to the hospital’s electronic health record system in order to perform their duties); *see also Daubert*, 509 U.S. at 593 (holding that “publication (or lack thereof) in a peer reviewed journal” is a relevant but not dispositive factor in evaluating admissibility of expert testimony); *cf. United States v. Hankey*, 203 F.4d 1160, 1169 (9th Cir. 2000) (permitting police officer to testify about gang membership and tenets because information he relied upon in reaching his conclusions was “of the type normally obtained in his day-to-day police activity.”)

B. Plaintiffs’ experts are permitted to base their opinions in part on other experts’ testimony.

Because this litigation focuses on the design, development, and marketing of Bard’s IVC filters and involves so many different technical and scientific disciplines, many of Plaintiffs’ experts rely on the reports of other experts for background and data.

1 In particular, the Rule 26 report of Plaintiffs’ regulatory expert Dr. David Kessler—which
2 includes a detailed history of Bard’s filters—serves as a source of underlying information
3 for other Plaintiff experts in developing their own opinions. There is nothing improper
4 about this practice. In complex cases where the parties offer opinions of multiple experts,
5 it is not uncommon for an expert to base an opinion in part on the testimony of other
6 expert witnesses with more specialized knowledge. *In re Toyota Motor Corp. Unintended*
7 *Acceleration Mktg., Sales Practices, and Prods. Liab. Litig.*, 978 F. Supp. 2d 1053, 1066
8 (C.D. Cal. 2013) (holding that “expert opinions may find a basis in part on what a
9 different expert believes on the basis of expert knowledge not possessed by the first
10 expert” (internal quotation marks omitted)). Such testimony is admissible as long as the
11 expert does not merely act as a conduit for the other expert’s opinion and provided that the
12 record shows that the expert independently evaluated the evidence supporting the other
13 expert’s opinion. *Id.*; *Jerpe v. Aerospatiale*, No. CIV. S–03–555 LKK/DAD, 2007 WL
14 1394969, at *6 (E.D. Cal. May 10, 2007); *Gray v. United States*, No. 05cv1893 J(BLM),
15 2007 WL 4644736, at *8 (S.D. Cal. Mar. 17, 2007).

16 Plaintiffs’ experts primarily cite to the work of other experts for factual
17 background, in particular Dr. Kessler’s detailed recitation of the factual basis for his
18 opinions. Reliance by experts on facts and information provided by other experts to
19 formulate their opinions is unremarkable and has been approved in many different
20 contexts. *See Mesfun v. Hagos*, No. CV 03-02182 MMM (RNBx), 2005 WL 5956612, at
21 *18 (C.D. Cal. Feb. 16, 2005) (“Experts are permitted to rely on hearsay, including the
22 opinions of other experts, if proper foundation is laid that others in the field would
23 likewise rely on them.”). And to the extent any of Plaintiffs’ experts can be considered to
24 be relying on the opinions of Dr. Kessler or anyone else, as opposed to just factual
25 background or factual support in Dr. Kessler’s and other reports, they also considered a
26 wealth of other data for their opinions. *See In re Toyota*, 978 F. Supp. 2d at 1071 (finding
27 that plaintiff’s expert’s opinion was admissible because he reviewed other types of data,
28 not solely the opinions of other experts). The specifics of what each expert reviewed can

1 be found in their individual expert reports and are discussed in more detail—to the extent
2 necessary—in their specific response briefs.

3 Finally, none of Plaintiffs’ experts are simply “parroting” other experts’ opinions.
4 Despite Bard’s criticisms, agreement among Plaintiffs’ experts does not hinder the
5 reliability of their analysis because it is consistent with their own research. To the extent
6 that Bard believes this agreement is suspect, it is free to cross-examine the experts on it at
7 trial; the mere fact that many of Plaintiffs’ experts reach similar conclusions based on the
8 same evidence is not grounds for exclusion.

9 **C. Plaintiffs’ experts have not and will not opine on Bard’s state of mind**
10 **or the ethics of its or its employees’ actions, but can discuss what**
11 **knowledge Bard possessed at a given time based on evidence in the**
12 **record.**

13 Bard asserts that several of Plaintiffs’ experts must not be permitted to offer
14 opinions concerning “corporate intent and ethics.” Specific examples are discussed in the
15 individual response briefs. But in general, expert testimony about what Bard knew at
16 various points in the development of its retrievable IVC filters is purely factual and based
17 on documentary evidence produced by Bard. For example, Plaintiffs’ experts may use
18 Bard internal documents to explain that Bard had notice from the Asch study in 2002 of
19 problems with its filters fracturing, or that it was aware of early reports of caudal
20 migrations with the G2 filters. These are statements of fact based on the record, not
21 improper “mens rea” or “corporate intent” opinions as Bard mischaracterizes them.

22 These types of arguments have already been rejected in this litigation. In *Tillman*
23 *v. C.R. Bard, Inc.*, 96 F. Supp. 3d 1307 (M.D. Fla. 2015), a pre-MDL ruling from a
24 Florida IVC filter case, the district court permitted plaintiff’s engineering experts to testify
25 that Bard’s conduct was “incompetent” and “misleading” and expressly denied Bard’s
26 assertion that such opinions related to the company’s intent or state of mind:

27 [T]he Engineers also opine that it is misleading for Bard to claim
28 that G2 filters are twelve times more fatigue resistant than
Recovery filters, and upon consideration, the Court finds this
opinion to be permissible. [Citation omitted]. The Engineers
reviewed the testing done to support Bard’s claim and determined

1 that the claim is misleading based on their analysis of what the
2 testing actually showed. *An opinion that Bard's claim was*
3 *misleading because it was not supported by the tests performed*
does not relate to legal standards, nor is it a question of Bard's
state of mind or intent.

4 *Id.* at 1327 (emphasis added); cf. *Phillips v. C.R. Bard, Inc.*, 3:12-CV-00344-R CJ, 2014
5 WL 7177256, **5-6 (D. Nev. Dec. 16, 2014) (denying, in pre-MDL Bard IVC filter case,
6 Bard motion to exclude plaintiff's regulatory expert Suzanne Parisian, M.D.). The Court
7 should apply the same reasoning here.

8 Plaintiffs' experts will not opine as to whether Bard's conduct was "unethical," nor
9 will they express opinions about what Bard's intentions or motivations were. But they
10 will discuss what facts Bard possessed and knew at various points in Bard's development
11 and marketing of its IVC filters, and whether it was misleading for Bard not to disclose all
12 that it knew about its IVC filters and their risks with physicians and the public. There is
13 nothing improper about such testimony.

14
15 **D. Plaintiffs' experts may reasonably base their testimony in part on**
16 **Bard's documents and employee testimony, and their opinions that rely**
on those documents and testimony will be helpful to the jury.

17 As the Court is aware, this litigation involves multiple iterations of a medical
18 device, the first of which went to market nearly fifteen years ago. The entire history of
19 Bard's development of its IVC filters is of particular relevance because thousands of
20 plaintiffs allege they were injured by all of Bard's IVC filter models and through a variety
21 of different failure modes (fracture, migration, perforation, etc.). The Bard documents
22 and witness deposition testimony describing that history are necessarily voluminous.
23 Plaintiffs' experts—in particular their regulatory experts—must thoroughly describe this
24 history and the supporting evidentiary record to reach their conclusions. There is nothing
25 improper in doing so, and in fact such detail is necessary in order to lay a proper
26 foundation for their opinions.

27 Bard complains that Plaintiffs' experts rely on a relatively small number of
28 representative documents from Bard's production to support their opinions. This

1 argument is specious. In every litigation, each party selects a subset of documents
2 produced in discovery to use (were it otherwise, trials would last years, and jurors would
3 be overwhelmed by mountains of unhelpful exhibits). Notably, even Bard's own experts
4 have testified that the documents identified by Plaintiffs as important would have been
5 useful to them in identifying their own opinions. *See* Exh. 1, Moritz Dep. at 31:22-33:2
6 (Dr. Moritz inquired with Bard about the Bard internal documents that Plaintiffs' experts,
7 including Dr. Kessler, had reviewed but they were not provided to him). Moreover, Bard
8 had the opportunity at their depositions to present all of Plaintiffs' experts with its internal
9 documents that it believes refutes the experts' opinions. Bard will also have this
10 opportunity to do so at trial during cross-examination (to the extent these documents
11 exist), which is where this point should be made, if at all.

12 Many of the documents Plaintiffs will use at trial involve complex technical and
13 scientific information and require expertise to explain those exhibits and put them in their
14 proper context. It is appropriate for Plaintiffs' experts to serve in that role. The Ninth
15 Circuit has recognized "the importance of expert testimony when an issue appears to be
16 within the parameters of a layperson's common sense, but in actuality, is beyond their
17 knowledge." *U.S. v. Finley*, 301 F.3d 1000 (9th Cir. 2002); *see also Poosh v. Philip*
18 *Morris, USA, Inc.*, 287 F.R.D. 543, 553 (N.D. Ca. 2012) ("To the extent that the
19 documents discuss complex scientific theories, and that information is within [the
20 plaintiffs' epidemiologist's] area of expertise, the court would permit the testimony.").

21 Nor is there anything improper about providing a factual description of the long
22 and detailed history of the problems with Bard's IVC filters in an expert's report, despite
23 Bard's "narrative" objections raised in several motions. The Ninth Circuit has permitted
24 expert witnesses to provide narratives and factual summaries of corporate documents that
25 help the jury understand complex issues and background information in similar litigation.
26 *Staub v. Breg, Inc.*, No. CV 10-02038-PHX-FJM, 2012 WL 1078335, at *3 (D. Ariz. Mar.
27 30, 2012) (allowing the plaintiffs' regulatory expert in medical device litigation to testify
28 at trial despite objections that her report was a narrative as long as expert provided "some

analysis, opinion, or expertise when testifying” and noting that narrative testimony objections were “best made at trial”); *Johnson v. Wyeth LLC*, No. CV 10-02690-PHX-FJM, 2012 WL 1204081, at *3 (D. Ariz. Apr. 11, 2012) (same); *United States v. Newmont USA Ltd.*, No. CV-05-020-JLQ, 2007 WL 4856859, at *3 (E.D. Wash. Nov. 16, 2007) (the fact that expert’s opinion was “based upon a narrative of facts based upon his own review of documentary evidence already in the record” did not render expert’s testimony inadmissible). Nor is “Narrative” a proper basis for excluding a witness or their opinions under Rule 702 or *Daubert*. “The objection that testimony is ‘narrative’ is an objection to form, foundation or responsiveness, and must be presented at trial” *In re Actos (Pioglitazone) Products Liab. Litig.*, No. 12-cv-00064, 2014 WL 120973, at *10 (W.D. La. Jan. 10, 2014); *see also In re Yasmin & YAZ (Drospirenone) Mktg., Sales Practices & Products Liab. Litig.*, No. 3:09-md-02100-DRH-PMF, MDL No. 2100, 2011 WL 6302287, at *13 (S.D. Ill. Dec. 16, 2011) (holding that objections to Dr. Kessler’s expert testimony on the grounds that his “factual narratives and summaries of Bayer documents are not the proper subject of expert testimony” should be decided in context of trial).

Finally, Bard mistakenly argues that Plaintiffs’ experts violate Rule 703 by considering Bard’s documents and employee witness testimony obtained in this litigation as a basis for their opinions because they do not typically rely on such data in the course of their professional research. The law requires all experts to testify on technical matters within confines imposed by rules of evidence and procedure, at times considering relevant information provided to them through discovery. By necessity, legal testimony is inherently different from what researchers do in the academic context. Rule 703 does not bar experts from considering relevant and reliable evidence they have been made aware of simply because they wouldn’t normally have access to it in their field of practice.

III. CONCLUSION

Based on the foregoing reasons, Plaintiffs respectfully request that the Court deny in full all of Bard’s motions to exclude Plaintiffs’ experts or their opinions.

1 RESPECTFULLY SUBMITTED this 27th day of September, 2017.

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13 **CERTIFICATE OF SERVICE**

14 I hereby certify that on this 27th day of September, 2017, I electronically
15 transmitted the attached document to the Clerk's Office using the CM/ECF System for
16 filing and transmittal of a Notice of Electronic Filing.

17 /s/ Gay Mennuti